

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
 US Department of Commerce
 United States Patent and Trademark
 Office, PCT
 2011 South Clark Place Room
 CP2/5C24
 Arlington, VA 22202
 ETATS-UNIS D'AMERIQUE
 in its capacity as elected Office

Date of mailing (day/month/year) 31 May 2001 (31.05.01)	Applicant's or agent's file reference Schu6
International application No. PCT/AU00/01159	Priority date (day/month/year) 24 September 1999 (24.09.99)
International filing date (day/month/year) 25 September 2000 (25.09.00)	
Applicant RUDOV, David	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
 23 April 2001 (23.04.01)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer J. Leitao Telephone No.: (41-22) 338.83.38
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 00/01159**A. CLASSIFICATION OF SUBJECT MATTER**Int Cl⁷: A61K 35/78, A61P1/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHEDMinimum documentation searched (classification system followed by classification symbols)
IPC: A61K 35/78, A61P 1/00Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
AU: IPC as aboveElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WPAT: Cereal, Rye, Ryegrass, Secale Cereals, Barley, Wheat, Triticum, T Durum, T Compactum, Triticale, Corn, Rice, Oats, Maize, Sorghum, Millet, Extract, Side effects, Indigestion, Gas Production, Eructation, Constipation, Diarrhoea, Rash, Headache, Nausea, Dizziness**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
X	WO 91/11191 A (RUDOV DAVID) 8 August 1991 Whole document	7,9-12 23,25-28
X	US 3787591 A (YOSHIHIDE HAGIWARA) 22 January 1974 Whole document	7,9-12,23, 25-28
X	AU 81985/87 A (RUDOV DAVID) 9 June 1988 Whole document	1,3-7,9-13, 15-23,25-29,31-38

☒ Further documents are listed in the
continuation of Box C☒ See patent family annex

* Special categories of cited documents:

"A" Document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search
2 November 2000Date of mailing of the international search report
14 NOV 2000

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 00/01159

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	Patent Abstract of Japan, JP 2000044459 (TEKUNO BURU: KK) 15 February 2000	1,3-7,9-13, 15-23,25-29,31-38
X	EP 0620007 A (SOKEN CO.LTD) 19 October 1994 Whole document	1,3-7,9-13, 15-23,25-29,31-38
X	CN 1098851 (TAIPINGYANG SCIENCE AND TECH I (CN) 22 February 1995	1,3-7,9-13, 15-23,25-29,31-38
X	CN 1106227 (ZHENXING ROODSTUFF FACTORY SHE (CN) 9 August 1995	1,3-7,9-13,15-23,25- 29,31-38
X	WO 95/06459 A (HELSINKI UNIVERSITY LICENSING LTD) 9 March 1995 Whole document	1,3-7,9-13, 15-23,25-29,31-38
A	HIDVEGI ET AL, CANCER BIOTHERAPY AND RADIO PHARMACEUTICALS (1999) 14, No.4, 277-289	1-38
X	BHATTACHARYA ET AL, SCANDINAVIAN JOURNAL OF GASTROENTEROLOGY (1998) 33, 159-163	1,3-7,9-13,15-23, 25,29,31-38

INTERNATIONAL SEARCH REPORT

Information on patent family members

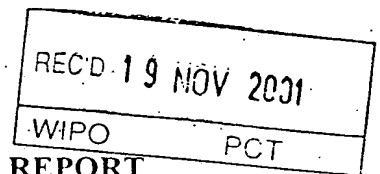
International application No.
PCT/AU 00/01159

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
WO	91/11191	AU	72175/91				
US	3787591	NONE					
AU	81985/87	CA	1298558	DK	6335/87	EP	279984
		HK	1184/94	NZ	222758	SG	1087/94
		US	4943433	WO	88/04176		
JP	00044459	NONE					
EP	620007	CA	2115707	JP	6298658	US	5728384
CN	1098851	NONE					
CN	1106227	NONE					
WO	95/06459	AU	75384/94	EP	717613	FI	933833
END OF ANNEX							

INTERNATIONAL COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



14

Applicant's or agent's file reference Schu6	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).	
International Application No. PCT/AU00/01159	International Filing Date (day/month/year) 25 September 2000	Priority Date (day/month/year) 24 September 1999
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ A61K 35/78, A61P 1/00		
Applicant RUDOV, David		

1.	This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2.	This REPORT consists of a total of 3 sheets, including this cover sheet. <input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of 7 sheet(s).

3. This report contains indications relating to the following items:	
I	<input checked="" type="checkbox"/> Basis of the report
II	<input type="checkbox"/> Priority
III	<input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	<input type="checkbox"/> Lack of unity of invention
V	<input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement
VI	<input type="checkbox"/> Certain documents cited
VII	<input type="checkbox"/> Certain defects in the international application
VIII	<input type="checkbox"/> Certain observations on the international application

Date of submission of the demand 23 April 2001	Date of completion of the report 1 November 2001
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer SHUBHRA CHANDRA Telephone No. (02) 6283 2264

PCT/AU00/01159

I. Basis of the report1. With regard to the **elements** of the international application:*

- ☐ the international application as originally filed.
- ☒ the description, pages **1-10**, as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages **11-17**, received on **31 August 2001** with the letter of **31 August 2001**
- ☐ the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ Contained in the international application in written form.
- ☐ Filed together with the international application in computer readable form.
- ☐ Furnished subsequently to this Authority in written form.
- ☐ Furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims 1-37	YES
	Claims	NO
Inventive step (IS)	Claims 1-37	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-37	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

D1 AU 81985/87

D2 Patent abstract of Japan, JP 2000044459

D3 EP 0620007

D4 CN 1098851

D5 CN 1106227

D6 WO 95/06459

D7 BHATTACHARYA ET AL SCANDINAVIAN JOURNAL OF GASTROENTROLOGY (1998) 33, 159-163.

D8 WO 91/11191

D9 US 3787591

None of the above mentioned citations disclose or suggest the invention as defined in the amended claims.
Therefore, Claims 1-37 are novel and inventive.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
5 April 2001 (05.04.2001)

PCT

(10) International Publication Number
WO 01/22980 A1

- (51) International Patent Classification⁷: **A61K 35/78**, (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
- A61P 1/00
- (21) International Application Number: PCT/AU00/01159
- (22) International Filing Date:
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- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
PQ 3050 24 September 1999 (24.09.1999) AU
PQ 4064 16 November 1999 (16.11.1999) AU
- (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
- (71) Applicant and
(72) Inventor: RUDOV, David [AU/AU]; 252 Collins Street, Melbourne, VIC 3000 (AU).
- Published:
— With international search report.
- (74) Agent: GRANT, Michael, John; Patent Attorney Services, 26 Ellingworth Parade, Box Hill, VIC 3128 (AU).
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SIDE EFFECTS TREATMENT

(57) Abstract: The invention provides a novel use of a substance comprising a pharmaceutically acceptable liquid extract from a juice derived from cereal plants (which includes wild grasses) and carried in a pharmaceutically acceptable carrier or excipient for application to and take up by an animal subject. The use is for the manufacture of a product for the adjunct treatment of animals including humans, to reduce the incidence or severity of side effects associated with primary chemical treatment of the animal. The invention also provides a product for the adjunct treatment of animals, a process for the adjunct treatment of animals, an adjunct secondary treatment product effective to reduce the incidence or severity of side effects, and a process for enhancing the therapeutic treatment of an animal.

WO 01/22980 A1

SIDE EFFECTS TREATMENT

This invention relates to processes and products for the treatment of animals, including humans, to reduce side effects associated with other chemical treatment regimes.

The treatment of animals including veterinary treatment of domestic animals, sporting
5 animals such as race horses, and livestock by use of chemical substances (including systemic and local treatments by ingestion, intravenous, and subcutaneous application as well as by external or topical application) frequently leads to undesirable side effects of the treatment regime. There is a very wide range of such side effects such as effects caused by systemic circulation of the treatment substances or caused by by-products or caused by
10 reaction products. Such side effects include for example rashes, headaches, nausea, dizziness, vision difficulties, circulatory problems and disorders, as well as general or local sensations of pain. Other side effects include gastrointestinal problems, e.g. reflux, indigestion, gas production and eructation, constipation, diarrhoea. The side effects can be due to toxic or allergic reactions by the subject as well as being effects of the mechanisms of
15 the substances. For example, the use of antibiotics is frequently associated with digestive problems when taken by ingestion due to the action of the antibiotics in inhibiting or killing normally present and beneficial micro-organisms in the digestive tract.

Antibiotics are frequently prescribed and used in the treatment of animals, including humans, for micro-organism infections, particularly bacterial infections and undesired side
20 effects of the antibiotics of the general kind outlined above are observed. Such side effects frequently require separate treatment, such as treatment with antihistamines to manage mild allergic responses.

The condition known as "chronic fatigue syndrome" or "CFS" is believed to be caused or associated with bacterial infection and is therefore known to be treated with

antibiotics. Undesired side effects are therefore associated with treatment of CFS patients with antibiotics.

The administration of antibiotics to animals, including human patients, both before, during and after surgery or other interventions including intrusive examinations is common.

5 Such administration of antibiotics is carried out to avoid or reduce trauma that may be commonly associated with the procedures. For example, respiratory infections, including bacterial and viral infections, are commonly encountered in post operative patients because patients are more susceptible at such times due to the immune system being compromised or more vulnerable following the traumatic procedures and due also to the condition for which

10 the procedure has been carried out. The administration of antibiotics in such circumstances is a frequently used as a precautionary measure. The antibiotics are frequently administered intravenously together with other substances such as saline solutions, analgesics, sedatives. The administration of antibiotics or other chemical treatments as precautionary or preventative treatments before, during or after traumatic events or during immuno

15 compromised or vulnerable conditions can be associated with the undesired side effects of the kind discussed above.

It is an object of the present invention to provide methods and products for reducing the incidence or severity of undesired side effects associated with chemical treatments of animals, including humans.

20 According to the present invention there is provided a method of treating an animal, including a human, e.g. for a pathological or injured or abnormal condition or for precautionary or preventative treatment before during or after a traumatic event or immuno compromised or vulnerable condition of the animal, the method including a primary chemical treatment involving the administration of a primary substance, the primary

treatment substance being selected from the group of treatment substances for animals including antibiotics and other pharmacologically effective substances for treating animals. the administration of such primary substance being commonly or occasionally associated with undesirable side effects being experienced by the animal. the method of treating further comprising administering to the animal. in conjunction with the administration of the primary treatment substance, a pharmacologically or therapeutically effective amount of a secondary substance to reduce the incidence or severity of the side effects, the secondary substance including an extract from cereal plants, the extract comprising a pharmaceutically acceptable extract derived from juice of cereal plants, the extract being carried in a pharmaceutically acceptable base carrier or excipient enabling the secondary substance to be taken up by the animal being treated.

The treatment of an animal, including a human, with a primary treatment substance having undesirable side effects with the secondary substance as an adjunct to the primary treatment is based on the unexpected and surprising reduction of the incidence or severity of the side effects resulting apparently from the adjunct treatment. For example, it has been observed that in the treatment of CFS using antibiotics, the normally or occasionally expected and observed side effects of the antibiotic treatment regime were significantly reduced in subjects having the adjunct treatment with the secondary substance according to the process of the present invention.

Likewise, it has been observed that the treatment of race horses for injured or pathological conditions involving administration of chemical substances such as antibiotics, has frequently necessitated the horses being rested or "spelled" or "turned out" for several months due to side effects of the primary treatment. However the administration of a secondary substance in accordance with the present invention to the animals as an adjunct to

the primary treatment has surprisingly led to horses following thorough veterinary inspections being declared fit to be raced again after much shorter resting or spelling periods.

Broadly the secondary substance used in the present invention comprises a
5 pharmaceutically acceptable liquid extract from a juice derived from cereal plants (which includes wild grasses) and carried in a pharmaceutically acceptable carrier or excipient for application to and take up by an animal subject. Such a substance will be referred to in this specification as "a substance of the kind described".

The references throughout this specification to a primary chemical treatment are
10 intended to cover any treatment with a foreign substance or material, whether by external, topical, transdermal, subcutaneous, intravenous application or by ingestion, the foreign substance or material including pharmaceuticals, herbal or naturopathic substances, and organic and inorganic elements or compounds, and carriers or excipients therefor.

According to a first particular aspect of the present invention, there is provided a
15 novel use of the substance of the kind described for the manufacture of a product for the adjunct treatment of animals including humans, to reduce the incidence or severity of side effects associated with primary chemical treatment of the animal.

According to a second particular aspect of the present invention there is provided a
product for the adjunct treatment of animals, including humans, the product comprising a
20 substance of the kind described in an effective quantity to reduce the incidence or severity of side effects associated with primary chemical treatment of the animal.

In a third particular aspect of the present invention there is provided a process for the adjunct treatment of animals, including humans, undergoing a primary chemical treatment, the process including the steps of administering an effective quantity of a substance of the

kind described to the animal in a manner and over a period of time to reduce the incidence or severity of side effects associated with primary chemical treatment of the animal.

In accordance with a fourth particular aspect of the present invention there is provided an adjunct secondary treatment product effective to reduce the incidence or severity of side effects associated with primary chemical treatment of the animal. the product comprising a substance of the kind described provided in a concentration and medium for administration to the animal to achieve the side effect reduction.

In a fifth particular aspect of the present invention there is provided a process for enhancing a therapeutic treatment of an animal by reducing the incidence or severity of side effects associated with a primary chemical treatment of the animal, the process comprising administering to the animal a substance of the kind described in a quantity and over a period of time to be effective to achieve the side effect reduction.

Preferably in the processes of the invention the administration of the adjunct secondary treatment substance occurs simultaneously with, and may also be continued after, the primary chemical treatment period.

A substance of the kind described is already known from Australian patent specification No. AU-81985/87 (Patent No. 599725) (equivalent US Pat. No. 4,943,433) by the present applicant. In this prior patent specification, a range of possible uses of the substance are described or indicated in passing. This earlier patent specification and subsequent uses of the commercial product produced according to the prior patent specification have resulted in recognition of range of physiological indications including anti-inflammatory, immunomodulatory, and analgesic activity. However, the activity of the substance of the kind described to reduce the incidence or severity of side effects associated with primary chemical treatment of the animal is totally unexpected and surprising leading

to novel new uses of the substance hitherto unknown and with no reason to expect or suspect or seek such new uses.

Reference may be made to AU-81985/87 for further background and description of a substance of the kind described useable in the present invention in its various aspects.

5 References herein to "cereal plants" is to be interpreted to include wild grasses. However, a particular cereal plant found to be particularly useful as a source of the extract is *Secale Cereale* or "rye grass".

Extracts from barley and wheat are also believed to be effective. The wheat may comprise *Triticum vulgare* or *aestivum*, *T. durum*, *T. compactum*, or *tritcale*. Corn, rice,
10 oats, maize, sorghum and millet may also be effective.

Preferably the extract is derived from the green leafy part of the plant, or at least principally from this part of the plant, although additional green parts such as stalk may be included. The leaves of the plant are preferably treated to yield the extract before the plant reaches flowering or seed production stage of development. That is, the plant is at its
15 unjointed or immature development stage.

The extraction is preferably carried out by squeezing, crushing and/or grinding processes, not by a cutting process.

Preferably the extract from the cereal plants comprises substantially only the water soluble components of the juice.

20 The plant extract may be used in the concentration in which it is derived from the plants. Alternatively, if desired, the extract may be concentrated and some or substantially all the liquid content of the plant extract may be removed. For example, the extracted plant matter may be dried, such as by spray drying to yield a powder for mixing with the carrier.

The spray drying is preferably carried out at a temperature of about 50°C and preferably below 60°C.

Other possible stabilisation processes for the juice include partial concentration of the derived juice to provide a concentrated liquid, freeze drying of the derived juice, and
5 blending the derived juice with a preserving agent forming an ingredient of the carrier.

Preferably the stabilisation or mixing with the carrier or both is carried out within a short time and preferably within two hours after extraction.

In an alternative possibility the extract may be produced by firstly drying plant matter after which the dried material is comminuted to yield a powder which includes ingredients
10 originally in the juice.

The carrier for the extract may be any suitable material such as a liquid (e.g. water or other solvent), cream, lotion, oil, gel or powder. For example the carrier may comprise a liquid in which the extract is dissolved or vanishing cream which is intended to be absorbed through the skin when applied so as to thereby carry the plant extract into sub-cutaneous
15 tissue. A water based or aqueous carrier capable of carrying water soluble ingredients to sub-surface tissues is preferred. Benzyl alcohol is a suitable carrier component for transdermal take up of the active ingredients.

The carrier for the extract may comprise the same carrier as used for the primary chemical treatment. For example, antibiotics can be administered to an animal in a lotion or
20 cream to be applied topically or externally. In such a case the substance of the kind described can be mixed with the primary treatment substance in the same carrier for simultaneous administration. Likewise, antibiotics or other primary treatment substances can be administered intravenously and, subject to obvious precautions concerning composition and concentrations, the substance of the kind described can be mixed with the

intravenous solution for simultaneous administration. Of course, it will be appreciated that the primary treatment substance and secondary treatment substance can be administered separately in their respective carriers. e.g. the primary substance intravenously and the secondary substance transdermally, or the primary substance by ingestion and the secondary substance by sublingual administration and transdermal absorption through oral mucous tissues.

Preferably the carrier includes an anti-microbial agent so as to kill or at least inhibit growth, reproduction or activity of contaminating organisms that may be present in the plant extract or may be introduced during production of the substance. Preferably the anti-microbial agent is an anti-bacterial agent. In addition or alternatively the agent may have anti-fungal and anti-yeast properties. The anti-microbial agent may be added to the substance during production or may be present in the carrier if the carrier for example is a standard commercially available product. The anti-microbial agent is preferably active to inhibit any activity of organisms and thereby is operative to inhibit spoilage of the substance, e.g. spoilage of the product when being stored by the user or by a commercial outlet.

If the anti-microbial is not provided, it is preferred that the extract is substantially sterile when mixed with the carrier. The plants from which the extract is derived may be grown hydroponically for example under sterile conditions to prevent the introduction of micro-organisms at that stage. The subsequent harvesting and processing may also be carried out under sterile conditions.

The ratio of the extract to the carrier may be anywhere within a large range of possible ratios. For example the ratio of base carrier to plant extract (and other additives if

provided) may be anywhere between 1 to 5 and 200 to 1 (by weight). A range of 1 to 30% by weight of extract is preferred.

Preferably the substance has a generally neutral pH in the range 6.0 to 8.0. For example, the pH may be in the range 6.5 to 7.5.

5 Use of the substance of the kind described to reduce the incidence or severity of side effects associated with primary chemical treatment of the animal is preferably by external application so that the substance is taken up by the body by absorption through the skin or mucous tissues. A particularly preferred method of transdermal uptake is by applying the substance to the mouth for uptake through mucous tissues of the mouth. For example, the
10 substance may be administered sublingually, e.g. in the form of drops of the substance taken orally and held in the mouth under the tongue for a short time. It is found that this method of administration is effective for uptake of the substance into the body. A suitable formulation is available commercially under the registered trade mark Oralmat, manufactured by Schumacher Pharmaceuticals Pty Ltd of Melbourne, Australia. This
15 formulation can be taken sublingually, three drops taken three times daily, to achieve the described beneficial effects.

It may also be possible (subject to obvious safeguards concerning the composition and concentration of the substance and carrier) to administer the substance subdermally by implant or injection.

20 The reduction of the incidence or severity of side effects associated with primary chemical treatment of the animal was unexpected and surprising and as yet the mechanism for this activity has not been determined. Indeed no obvious possible mechanism for the observed side effect reducing activity appears from the known physiological activities of the

substance according to the prior patent specification AU-81985/87 which have been seen over about the last ten years that might have suggested or predicted that activity.

The described effects of reducing incidence or severity of side effects have been observed in use of the secondary substance as a simultaneous adjunct treatment of patients
5 being treated for chronic fatigue syndrome with a primary treatment substance in the nature of an antibiotic.

The accelerated recovery with reduced or shortened incidence or severity of side effects has been observed in race horses undergoing primary chemical treatment for injury or pathological conditions.

10 These observed examples of reduction of the incidence or severity of side effects in chronic fatigue syndrome patients and in race horses indicate applicability of the present invention as an adjunct treatment for an animal, including a human, being treated for a pathological or injured or abnormal condition involving administration of a primary chemical treatment, particularly antibiotics. However, the observed advantageous effects in
15 side effects reduction indicates that the present invention is also applicable as a precautionary or preventative treatment, e.g. before, during or after a traumatic event or before, during or after an observed or expected immuno compromised or vulnerable condition, e.g. pre or post operative periods. The adjunct treatment of an animal according to the present invention promises a substantial reduction or amelioration of side effects in
20 such circumstances.

Claims

1. The use of a secondary substance for the manufacture of a product for the adjunct treatment of animals including humans to reduce the incidence or severity of side effects associated with a primary chemical treatment of the animal. the secondary substance
5 comprising a pharmaceutically acceptable liquid extract from a juice derived from cereal plants and carried in a pharmaceutically acceptable carrier or excipient for application to and take up by an animal subject.
2. The use as claimed in claim 1 wherein the juice is derived from rye grass (*Secale Cereale*).
- 10 3. The use as claimed in claim 1 or 2 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.
4. The use as claimed in any one of the preceding claims wherein the liquid extract comprises substantially only the water soluble components of the juice.
- 15 5. The use as claimed in any one of the preceding claims wherein the product includes both the secondary substance for the adjunct treatment mixed in the same carrier or excipient as the primary substance used for the primary chemical treatment whereby both the primary treatment substance and the secondary substance are administered to the subject simultaneously.
- 20 6. The use as claimed in claim 5 wherein the primary treatment substance comprises an antibiotic in a carrier or excipient for topical or external application to the subject, the secondary substance being mixed in the same carrier or excipient.
7. A substance for the adjunct treatment of animals including humans to reduce the incidence or severity of side effects associated with a primary chemical treatment of the

animal, the secondary substance comprising a pharmaceutically acceptable liquid extract from a juice derived from cereal plants and carried in a pharmaceutically acceptable carrier or excipient for application to and take up by an animal subject.

8. A substance as claimed in claim 7 wherein the juice is derived from rye grass (Secale
5 Cereale).

9. A substance as claimed in claim 7 or 8 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.

10. A substance as claimed in any one of claims 7 to 9 wherein the liquid extract comprises
10 substantially only the water soluble components of the juice.

11. A substance as claimed in any one of claims 7 to 10 wherein the product includes both the secondary substance for the adjunct treatment mixed in the same carrier or excipient as the primary substance used for the primary chemical treatment whereby both the primary treatment substance and the secondary substance are administered to the subject
15 simultaneously.

12. A substance as claimed in claim 11 wherein the primary treatment substance comprises an antibiotic in a carrier or excipient for topical or external application to the subject, the secondary substance being mixed in the same carrier or excipient.

13. A method of treating an animal, including a human, e.g. for a pathological or injured or
20 abnormal condition or for precautionary or preventative treatment before during or after a traumatic event or immuno compromised or vulnerable condition of the animal, the method including a primary chemical treatment involving the administration of a primary substance, the primary treatment substance being selected from the group of treatment substances for animals including antibiotics and other pharmacologically effective substances for treating

animals, the administration of such primary substance being commonly or occasionally associated with undesirable side effects being experienced by the animal, the method of treating further comprising administering to the animal, in conjunction with the administration of the primary treatment substance, a pharmacologically or therapeutically effective amount of a secondary substance to reduce the incidence or severity of the side effects, the secondary substance including an extract from cereal plants, the extract comprising a pharmaceutically acceptable extract derived from juice of cereal plants, the extract being carried in a pharmaceutically acceptable base carrier or excipient enabling the secondary substance to be taken up by the animal being treated.

10 14. A method as claimed in claim 13 wherein the juice is derived from rye grass (*Secale Cereale*).

15. A method as claimed in claim 13 or 14 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.

15 16. A method as claimed in any one of claims 13 to 15 wherein the liquid extract comprises substantially only the water soluble components of the juice.

17. A method as claimed in any one of claims 13 to 16 wherein the administration of the secondary substance occurs at least simultaneously with the administration of the primary treatment substance.

20 18. A method as claimed in any one of claims 13 to 17 wherein the administration of the secondary substance comprises external application to the animal of the secondary substance so that the secondary substance is taken up by the body by absorption through the skin or mucous tissues.

19. A method as claimed in claim 18 wherein the secondary substance is administered sub-lingually by administering the secondary substance orally to be held in the mouth and under the tongue.

20. A method as claimed any one of claims 13 to 19 wherein the primary substance
5 comprises an antibiotic substance.

21. A method as claimed in claim 20 wherein the animal comprises a human being treated for chronic fatigue syndrome by the administration of the antibiotic substance.

22. A method as claimed in claim 20 wherein the animal is a human undergoing treatment by administration of the antibiotic substance pre or post surgical procedure or intrusive
10 examination.

23. An adjunct secondary treatment substance for the adjunct treatment of animals including humans to reduce the incidence or severity of side effects associated with a primary chemical treatment of the animal, the secondary substance comprising a pharmaceutically acceptable liquid extract from a juice derived from cereal plants and
15 carried in a pharmaceutically acceptable carrier or excipient for application to and take up by an animal subject, the liquid extract being provided in a concentration for administration to the animal to achieve the side effect reduction.

24. An adjunct secondary treatment substance as claimed in claim 23 wherein the juice is derived from rye grass (*secale cereale*).

20 25. An adjunct secondary treatment substance as claimed in claim 23 or 24 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.

26. An adjunct secondary treatment substance as claimed in any one of claims 23 to 25 wherein the liquid extract comprises substantially only the water soluble components of the juice.

27. An adjunct secondary treatment substance as claimed in any one of claims 23 to 26
5 wherein the product includes both the secondary substance for the adjunct treatment mixed in the same carrier or excipient as the primary substance used for the primary chemical treatment whereby both the primary treatment substance and the secondary substance are administered to the subject simultaneously.

28. An adjunct secondary treatment substance as claimed in claim 27 wherein the primary
10 treatment substance comprises an antibiotic in a carrier or excipient for topical or external application to the subject, the secondary substance being mixed in the same carrier or excipient.

29. A method of enhancing the therapeutic treatment of an animal, including a human, e.g. for a pathological or injured or abnormal condition or for precautionary or preventative
15 treatment before during or after a traumatic event or immuno compromised or vulnerable condition of the animal, by reducing the incidence or severity of side effect associated with a primary chemical treatment involving the administration of a primary substance, the method comprising administering to the animal, in conjunction with the administration of the primary treatment substance, a pharmacologically or therapeutically effective amount of
20 a secondary substance to reduce the incidence or severity of the side effects, the secondary substance including an extract from cereal plants, the extract comprising a pharmaceutically acceptable extract derived from juice of cereal plants, the extract being carried in a pharmaceutically acceptable base carrier or excipient enabling the secondary substance to be

taken up by the animal being treated, the secondary substance administered being in a quantity and over a period of time to be effective to achieve the side effect reduction.

30. A method as claimed in claim 29 wherein the juice is derived from rye grass (*Secale Cereale*).

5 31. A method as claimed in claim 29 or 30 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.

32. A method as claimed in any one of claims 29 to 31 wherein the liquid extract comprises substantially only the water soluble components of the juice.

10 33. A method as claimed in any one of claims 29 to 32 wherein the administration of the secondary substance occurs at least simultaneously with the administration of the primary treatment substance.

34. A method as claimed in any one of claims 29 to 33 wherein the administration of the secondary substance comprises external application to the animal of the secondary
15 substance so that the secondary substance is taken up by the body by absorption through the skin or mucous tissues.

35. A method as claimed in claim 34 wherein the secondary substance is administered sub-lingually by administering the secondary substance orally to be held in the mouth and under the tongue.

20 36. A method as claimed any one of claims 29 to 35 wherein the primary substance comprises an antibiotic substance.

37. A method as claimed in claim 36 wherein the animal comprises a human being treated for chronic fatigue syndrome by the administration of the antibiotic substance.

38. A method as claimed in claim 36 wherein the animal is a human undergoing treatment by administration of the antibiotic substance pre or post surgical procedure or intrusive examination.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU 00/01159

A. CLASSIFICATION OF SUBJECT MATTERInt Cl⁷: A61K 35/78, A61P1/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHEDMinimum documentation searched (classification system followed by classification symbols)
IPC: A61K 35/78, A61P 1/00Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
AU: IPC as aboveElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WPAT: Cereal, Rye, Ryegrass, Secale Cereals, Barley, Wheat, Triticum, T Durum, T Compactum, Triticale, Corn, Rice, Oats, Maize, Sorghum, Millet, Extract, Side effects, Indigestion, Gas Production, Eructation, Constipation, Diarrhoea, Rash, Headache, Nausea, Dizziness**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No..
X	WO 91/11191 A (RUDOV DAVID) 8 August 1991 Whole document	7,9-12 23,25-28
X	US 3787591 A (YOSHIHIDE HAGIWARA) 22 January 1974 Whole document	7,9-12,23, 25-28
X	AU 81985/87 A (RUDOV DAVID) 9 June 1988 Whole document	1,3-7,9-13, 15-23,25-29,31-38

☒ Further documents are listed in the
continuation of Box C☒ See patent family annex

* Special categories of cited documents:		"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	Document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier application or patent but published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search
2 November 2000Date of mailing of the international search report
14 NOV 2000Name and mailing address of the ISA/AU
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INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU 00/01159

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	Patent Abstract of Japan, JP 2000044459 (TEKUNOOBURU: KK) 15 February 2000	1,3-7,9-13, 15-23,25-29,31-38
X	EP 0620007 A (SOKEN CO.LTD) 19 October 1994 Whole document	1,3-7,9-13, 15-23,25-29,31-38
X	CN 1098851 (TAIPINGYANG SCIENCE AND TECH 1 (CN) 22 February 1995	1,3-7,9-13, 15-23,25-29,31-38
X	CN 1106227 (ZHENXING ROODSTUFF FACTORY SHE (CN) 9 August 1995	1,3-7,9-13,15-23,25- 29,31-38
X	WO 95/06459 A (HELSINKI UNIVERSITY LICENSING LTD) 9 March 1995 Whole document	1,3-7,9-13, 15-23,25-29,31-38
A	HIDVEGI ET AL, CANCER BIOTHERAPY AND RADIO PHARMACEUTICALS (1999) 14, No.4, 277-289	1-38
X	BHATTACHARYA ET AL, SCANDINAVIAN JOURNAL OF GASTROENTEROLOGY (1998) 33, 159-163	1,3-7,9-13,15-23, 25,29,31-38

INTERNATIONAL SEARCH REPORT

Information on patent family members

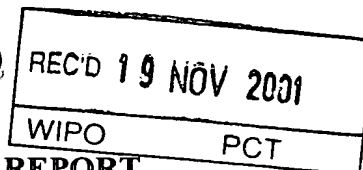
International application No.
PCT/AU 00/01159

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member			
WO	91/11191	AU	72175/91				
US	3787591	NONE					
AU	81985/87	CA	1298558	DK	6335/87	EP	279984
		HK	1184/94	NZ	222758	SG	1087/94
		US	4943433	WO	88/04176		
JP	00044459	NONE					
EP	620007	CA	2115707	JP	6298658	US	5728384
CN	1098851	NONE					
CN	1106227	NONE					
WO	95/06459	AU	75384/94	EP	717613	FI	933833
END OF ANNEX							

INTERNATIONAL COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



14

Applicant's or agent's file reference Schu6	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. PCT/AU00/01159	International Filing Date (day/month/year) 25 September 2000	Priority Date (day/month/year) 24 September 1999
International Patent Classification (IPC) or national classification and IPC Int. Cl.⁷ A61K 35/78, A61P 1/00		
Applicant RUDOV, David		

1.	This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.																
2.	<p>This REPORT consists of a total of 3 sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of 7 sheet(s).</p>																
3.	<p>This report contains indications relating to the following items:</p> <table style="width: 100%;"> <tr> <td style="width: 5%;">I</td> <td><input checked="" type="checkbox"/> Basis of the report</td> </tr> <tr> <td>II</td> <td><input type="checkbox"/> Priority</td> </tr> <tr> <td>III</td> <td><input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td>IV</td> <td><input type="checkbox"/> Lack of unity of invention</td> </tr> <tr> <td>V</td> <td><input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td>VI</td> <td><input type="checkbox"/> Certain documents cited</td> </tr> <tr> <td>VII</td> <td><input type="checkbox"/> Certain defects in the international application</td> </tr> <tr> <td>VIII</td> <td><input type="checkbox"/> Certain observations on the international application</td> </tr> </table>	I	<input checked="" type="checkbox"/> Basis of the report	II	<input type="checkbox"/> Priority	III	<input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	IV	<input type="checkbox"/> Lack of unity of invention	V	<input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	VI	<input type="checkbox"/> Certain documents cited	VII	<input type="checkbox"/> Certain defects in the international application	VIII	<input type="checkbox"/> Certain observations on the international application
I	<input checked="" type="checkbox"/> Basis of the report																
II	<input type="checkbox"/> Priority																
III	<input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability																
IV	<input type="checkbox"/> Lack of unity of invention																
V	<input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement																
VI	<input type="checkbox"/> Certain documents cited																
VII	<input type="checkbox"/> Certain defects in the international application																
VIII	<input type="checkbox"/> Certain observations on the international application																

Date of submission of the demand 23 April 2001	Date of completion of the report 1 November 2001
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer SHUBHRA CHANDRA Telephone No. (02) 6283 2264

I. Basis of the report

1. With regard to the **elements** of the international application:*
- ☐ the international application as originally filed.
- ☒ the description, pages **1-10**, as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages **11-17**, received on **31 August 2001** with the letter of **31 August 2001**
- ☐ the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of
2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:
- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:
- ☐ Contained in the international application in written form.
- ☐ Filed together with the international application in computer readable form.
- ☐ Furnished subsequently to this Authority in written form.
- ☐ Furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished
4. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.
5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims 1-37	YES
	Claims	NO
Inventive step (IS)	Claims 1-37	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-37	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

D1 AU 81985/87

D2 Patent abstract of Japan, JP 2000044459

D3 EP 0620007

D4 CN 1098851

D5 CN 1106227

D6 WO 95/06459

D7 BHATTACHARYA ET AL SCANDINAVIAN JOURNAL OF GASTROENTROLOGY (1998) 33, 159-163.

D8 WO 91/11191

D9 US 3787591

None of the above mentioned citations disclose or suggest the invention as defined in the amended claims.
Therefore, Claims 1-37 are novel and inventive.

Claims

1. The use of a secondary substance for the manufacture of a product for the adjunct
treatment of animals including humans to reduce the incidence or severity of side effects
5 associated with a primary chemical treatment of the animal, the secondary substance
comprising a pharmaceutically acceptable liquid extract from a juice derived from rye grass
(Secale Cereale) and carried in a pharmaceutically acceptable carrier or excipient for
application to and take up by an animal subject.
2. The use of a secondary substance for the manufacture of a product for the adjunct
10 treatment of animals including humans to reduce the incidence or severity of side effects
associated with a primary chemical treatment of the animal, wherein the product includes a
primary substance used for the primary chemical treatment and a secondary substance, the
primary substance being mixed in the same pharmaceutically acceptable carrier or excipient
as the secondary substance the secondary substance comprising a pharmaceutically
15 acceptable extract from a juice derived from cereal plants.
3. The use as claimed in claim 2 wherein the juice is derived from rye grass (Secale
Cereale).
4. The use as claimed in any one of the preceding claims wherein the extract is obtained
from juice derived from the green leafy parts of the plants harvested when the plants are at
20 the unjointed or immature development stage.
5. The use as claimed in any one of the preceding claims wherein the liquid extract
comprises substantially only the water soluble components of the juice.
6. The use as claimed in any one of the preceding claims wherein the primary treatment
substance comprises an antibiotic in a carrier or excipient for topical or external application
25 to the subject, the secondary substance being mixed in the same carrier or excipient.

7. A substance for the adjunct treatment of animals including humans to reduce the incidence or severity of side effects associated with a primary chemical treatment of the animal, the secondary substance comprising a pharmaceutically acceptable liquid extract
5 from a juice derived from rye grass (*Secale Cereale*) and carried in a pharmaceutically acceptable carrier or excipient for application to and take up by an animal subject.
8. A product for the treatment of animals including humans including a primary substance used for a primary chemical treatment of the animal and a secondary substance for the adjunct treatment of the animal to reduce the incidence or severity of side effects associated
10 with the primary chemical treatment, the primary substance being mixed in the same carrier or excipient as the secondary substance, the second substance comprising a pharmaceutically acceptable liquid extract from a juice derived from cereal plants, whereby both the primary substance and the secondary substance are administered to the subject simultaneously.
9. A substance as claimed in claim 8 wherein the juice is derived from rye grass (*Secale*
15 *Cereale*).
10. A substance as claimed in claim 7, 8 or 9 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.
11. A substance as claimed in any one of claims 7 to 10 wherein the liquid extract
20 comprises substantially only the water soluble components of the juice.
12. A substance as claimed in any one of claims 7 to 11 wherein the primary treatment substance comprises an antibiotic in a carrier or excipient for topical or external application to the subject, the secondary substance being mixed in the same carrier or excipient.

13. A method of precautionary or preventative treatment of an animal, including a human, of side effects associated with a traumatic event or immuno compromised or vulnerable condition of the animal, the method including a primary chemical treatment involving the
5 administration of a primary substance, the primary treatment substance being selected from the group of treatment substances for animals including antibiotics and other pharmacologically effective substances for treating animals, the administration of such primary substance being commonly or occasionally associated with undesirable side effects being experienced by the animal, the method of treating further comprising administering to
10 the animal, in conjunction with the administration of the primary treatment substance, a pharmacologically or therapeutically effective amount of a secondary substance to reduce the incidence or severity of the side effects, the secondary substance including an extract from cereal plants, the extract comprising a pharmaceutically acceptable extract derived from juice of cereal plants, the extract being carried in a pharmaceutically acceptable base
15 carrier or excipient enabling the secondary substance to be taken up by the animal being treated.
14. A method as claimed in claim 13 wherein the juice is derived from rye grass (*Secale Cereale*).
15. A method as claimed in claim 13 or 14 wherein the extract is obtained from juice
20 derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.
16. A method as claimed in any one of claims 13 to 15 wherein the liquid extract comprises substantially only the water soluble components of the juice.

17. A method as claimed in any one of claims 13 to 16 wherein the administration of the secondary substance occurs at least simultaneously with the administration of the primary treatment substance.
- 5 18. A method as claimed in any one of claims 13 to 17 wherein the administration of the secondary substance comprises external application to the animal of the secondary substance so that the secondary substance is taken up by the body by absorption through the skin or mucous tissues.
19. A method as claimed in claim 18 wherein the secondary substance is administered
10 sub-lingually by administering the secondary substance orally to be held in the mouth and under the tongue.
20. A method as claimed any one of claims 13 to 19 wherein the primary substance comprises an antibiotic substance.
21. A method as claimed in claim 20 wherein the animal comprises a human being treated
15 for chronic fatigue syndrome by the administration of the antibiotic substance.
22. A method as claimed in claim 20 wherein the animal is a human undergoing treatment by administration of the antibiotic substance pre or post surgical procedure or intrusive examination.
23. An adjunct secondary treatment substance for the adjunct treatment of animals
20 including humans to reduce the incidence or severity of side effects associated with a primary chemical treatment of the animal, the secondary substance comprising a pharmaceutically acceptable liquid extract from a juice derived from rye grass (*Secale Cereale*) and carried in a pharmaceutically acceptable carrier or excipient for application to

and take up by an animal subject, the liquid extract being provided in a concentration for administration to the animal to achieve the side effect reduction.

24. An adjunct secondary treatment substance as claimed in claim 23 wherein the extract is
5 obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.

25. An adjunct secondary treatment substance as claimed in claim 23 or claim 24 wherein the liquid extract comprises substantially only the water soluble components of the juice.

26. An adjunct secondary treatment substance as claimed in any one of claims 23 to 25
10 wherein the product includes both the secondary substance for the adjunct treatment mixed in the same carrier or excipient as the primary substance used for the primary chemical treatment whereby both the primary treatment substance and the secondary substance are administered to the subject simultaneously.

27. An adjunct secondary treatment substance as claimed in claim 26 wherein the primary
15 treatment substance comprises an antibiotic in a carrier or excipient for topical or external application to the subject, the secondary substance being mixed in the same carrier or excipient.

28. A method of enhancing the therapeutic treatment of an animal, including a human, e.g. for a pathological or injured or abnormal condition or for precautionary or preventative
20 treatment before during or after a traumatic event or immuno compromised or vulnerable condition of the animal, by reducing the incidence or severity of side effect associated with a primary chemical treatment involving the administration of a primary substance, the method comprising administering to the animal, in conjunction with the administration of the primary treatment substance, a pharmacologically or therapeutically effective amount of a

secondary substance to reduce the incidence or severity of the side effects, the secondary substance including an extract from cereal plants, the extract comprising a pharmaceutically acceptable extract derived from juice of cereal plants, the extract being carried in a
5 pharmaceutically acceptable base carrier or excipient enabling the secondary substance to be taken up by the animal being treated, the secondary substance administered being in a quantity and over a period of time to be effective to achieve the side effect reduction.

29. A method as claimed in claim 28 wherein the juice is derived from rye grass (*Secale Cereale*).

10 30. A method as claimed in claim 28 or 29 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.

31. A method as claimed in any one of claims 28 to 30 wherein the liquid extract comprises substantially only the water soluble components of the juice.

15 32. A method as claimed in any one of claims 28 to 31 wherein the administration of the secondary substance occurs at least simultaneously with the administration of the primary treatment substance.

33. A method as claimed in any one of claims 28 to 32 wherein the administration of the secondary substance comprises external application to the animal of the secondary substance
20 so that the secondary substance is taken up by the body by absorption through the skin or mucous tissues.

34. A method as claimed in claim 33 wherein the secondary substance is administered sub-lingually by administering the secondary substance orally to be held in the mouth and under the tongue.

35. A method as claimed any one of claims 28 to 34 wherein the primary substance comprises an antibiotic substance.
36. A method as claimed in claim 35 wherein the animal comprises a human being treated
5 for chronic fatigue syndrome by the administration of the antibiotic substance.
37. A method as claimed in claim 35 wherein the animal is a human undergoing treatment by administration of the antibiotic substance pre or post surgical procedure or intrusive examination.

Claims

1. The use of a secondary substance for the manufacture of a product for the adjunct treatment of animals including humans to reduce the incidence or severity of side effects associated with a primary chemical treatment of the animal, the secondary substance comprising a pharmaceutically acceptable liquid extract from a juice derived from cereal plants and carried in a pharmaceutically acceptable carrier or excipient for application to and take up by an animal subject.
2. The use as claimed in claim 1 wherein the juice is derived from rye grass (*Secale Cereale*).
3. The use as claimed in claim 1 or 2 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.
4. The use as claimed in any one of the preceding claims wherein the liquid extract comprises substantially only the water soluble components of the juice.
5. The use as claimed in any one of the preceding claims wherein the product includes both the secondary substance for the adjunct treatment mixed in the same carrier or excipient as the primary substance used for the primary chemical treatment whereby both the primary treatment substance and the secondary substance are administered to the subject simultaneously.
6. The use as claimed in claim 5 wherein the primary treatment substance comprises an antibiotic in a carrier or excipient for topical or external application to the subject, the secondary substance being mixed in the same carrier or excipient.
7. A substance for the adjunct treatment of animals including humans to reduce the incidence or severity of side effects associated with a primary chemical treatment of the

animal, the secondary substance comprising a pharmaceutically acceptable liquid extract from a juice derived from cereal plants and carried in a pharmaceutically acceptable carrier or excipient for application to and take up by an animal subject.

8. A substance as claimed in claim 7 wherein the juice is derived from rye grass (Secale
5 Cereale).
9. A substance as claimed in claim 7 or 8 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.
10. A substance as claimed in any one of claims 7 to 9 wherein the liquid extract comprises
10 substantially only the water soluble components of the juice.
11. A substance as claimed in any one of claims 7 to 10 wherein the product includes both the secondary substance for the adjunct treatment mixed in the same carrier or excipient as the primary substance used for the primary chemical treatment whereby both the primary treatment substance and the secondary substance are administered to the subject
15 simultaneously.
12. A substance as claimed in claim 11 wherein the primary treatment substance comprises an antibiotic in a carrier or excipient for topical or external application to the subject, the secondary substance being mixed in the same carrier or excipient.
13. A method of treating an animal, including a human, e.g. for a pathological or injured or
20 abnormal condition or for precautionary or preventative treatment before during or after a traumatic event or immuno compromised or vulnerable condition of the animal, the method including a primary chemical treatment involving the administration of a primary substance, the primary treatment substance being selected from the group of treatment substances for animals including antibiotics and other pharmacologically effective substances for treating

- animals, the administration of such primary substance being commonly or occasionally associated with undesirable side effects being experienced by the animal, the method of treating further comprising administering to the animal, in conjunction with the administration of the primary treatment substance, a pharmacologically or therapeutically effective amount of a secondary substance to reduce the incidence or severity of the side effects, the secondary substance including an extract from cereal plants, the extract comprising a pharmaceutically acceptable extract derived from juice of cereal plants, the extract being carried in a pharmaceutically acceptable base carrier or excipient enabling the secondary substance to be taken up by the animal being treated.
- 10 14. A method as claimed in claim 13 wherein the juice is derived from rye grass (*Secale Cereale*).
- 15 15. A method as claimed in claim 13 or 14 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.
- 15 16. A method as claimed in any one of claims 13 to 15 wherein the liquid extract comprises substantially only the water soluble components of the juice.
17. A method as claimed in any one of claims 13 to 16 wherein the administration of the secondary substance occurs at least simultaneously with the administration of the primary treatment substance.
- 20 18. A method as claimed in any one of claims 13 to 17 wherein the administration of the secondary substance comprises external application to the animal of the secondary substance so that the secondary substance is taken up by the body by absorption through the skin or mucous tissues.

19. A method as claimed in claim 18 wherein the secondary substance is administered sub-lingually by administering the secondary substance orally to be held in the mouth and under the tongue.
20. A method as claimed any one of claims 13 to 19 wherein the primary substance
5 comprises an antibiotic substance.
21. A method as claimed in claim 20 wherein the animal comprises a human being treated for chronic fatigue syndrome by the administration of the antibiotic substance.
22. A method as claimed in claim 20 wherein the animal is a human undergoing treatment by administration of the antibiotic substance pre or post surgical procedure or intrusive
10 examination.
23. An adjunct secondary treatment substance for the adjunct treatment of animals including humans to reduce the incidence or severity of side effects associated with a primary chemical treatment of the animal, the secondary substance comprising a pharmaceutically acceptable liquid extract from a juice derived from cereal plants and
15 carried in a pharmaceutically acceptable carrier or excipient for application to and take up by an animal subject, the liquid extract being provided in a concentration for administration to the animal to achieve the side effect reduction.
24. An adjunct secondary treatment substance as claimed in claim 23 wherein the juice is derived from rye grass (*secale cereale*).
- 20 25. An adjunct secondary treatment substance as claimed in claim 23 or 24 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.

26. An adjunct secondary treatment substance as claimed in any one of claims 23 to 25 wherein the liquid extract comprises substantially only the water soluble components of the juice.
27. An adjunct secondary treatment substance as claimed in any one of claims 23 to 26
5 wherein the product includes both the secondary substance for the adjunct treatment mixed in the same carrier or excipient as the primary substance used for the primary chemical treatment whereby both the primary treatment substance and the secondary substance are administered to the subject simultaneously.
28. An adjunct secondary treatment substance as claimed in claim 27 wherein the primary
10 treatment substance comprises an antibiotic in a carrier or excipient for topical or external application to the subject, the secondary substance being mixed in the same carrier or excipient.
29. A method of enhancing the therapeutic treatment of an animal, including a human, e.g. for a pathological or injured or abnormal condition or for precautionary or preventative
15 treatment before during or after a traumatic event or immuno compromised or vulnerable condition of the animal, by reducing the incidence or severity of side effect associated with a primary chemical treatment involving the administration of a primary substance, the method comprising administering to the animal, in conjunction with the administration of the primary treatment substance, a pharmacologically or therapeutically effective amount of
20 a secondary substance to reduce the incidence or severity of the side effects, the secondary substance including an extract from cereal plants, the extract comprising a pharmaceutically acceptable extract derived from juice of cereal plants, the extract being carried in a pharmaceutically acceptable base carrier or excipient enabling the secondary substance to be

taken up by the animal being treated, the secondary substance administered being in a quantity and over a period of time to be effective to achieve the side effect reduction.

30. A method as claimed in claim 29 wherein the juice is derived from rye grass (*Secale Cereale*).
- 5 31. A method as claimed in claim 29 or 30 wherein the extract is obtained from juice derived from the green leafy parts of the plants harvested when the plants are at the unjointed or immature development stage.
32. A method as claimed in any one of claims 29 to 31 wherein the liquid extract comprises substantially only the water soluble components of the juice.
- 10 33. A method as claimed in any one of claims 29 to 32 wherein the administration of the secondary substance occurs at least simultaneously with the administration of the primary treatment substance.
34. A method as claimed in any one of claims 29 to 33 wherein the administration of the secondary substance comprises external application to the animal of the secondary
15 substance so that the secondary substance is taken up by the body by absorption through the skin or mucous tissues.
35. A method as claimed in claim 34 wherein the secondary substance is administered sub-lingually by administering the secondary substance orally to be held in the mouth and under the tongue.
- 20 36. A method as claimed any one of claims 29 to 35 wherein the primary substance comprises an antibiotic substance.
37. A method as claimed in claim 36 wherein the animal comprises a human being treated for chronic fatigue syndrome by the administration of the antibiotic substance.

38. A method as claimed in claim 36 wherein the animal is a human undergoing treatment by administration of the antibiotic substance pre or post surgical procedure or intrusive examination.